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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,169	02/25/2002	Jose Castillo Deniega	IFLOW.063DV1	3825

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/085,169	DENIEGA ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: on page 1 of the specification, after "1999", --now U.S.. Patent No. 6,350,253—should be inserted.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-3, 5-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampropoulos et al., 5,817,072, in view of Abiuso et al., 5,213,576, and further in view of Loeffler, 5,891,154, and Saab, 5,624,392.

Lampropoulos et al. disclose the invention substantially as claimed.

As to claims 1 and 5, Lampropoulos et al. disclose an elongated tube having a plurality of exit holes increasing in size along the length of the catheter (column 7, lines 57-67), so that a fluid flowing therein will flow through substantially all of said exit holes at a substantially equal rate (column 7, lines 57-67).

However, Lampropoulos et al. do not disclose that the exit slots are normally open. (Rather, Lampropoulos et al. disclose that the exit slots are normally closed.)

However Abiuso et al. teach a catheter for delivery of medicine wherein the medicine is pressurized through holes (col. 3, lines 56-62, and see figure 4). Moreover, Abiuso et al. teach that any of holes (32, 34) in any embodiment may be replaced by slits, particularly slits having sides that close together in the absence of a pressure differential thereacross, and Abiuso et al. disclose that such slits are intended to be included in the term "holes" (see col. 5, lines 25-29). Thus, Abiuso et al. teach that holes and slits are functional equivalents. That is, Abiuso et al. teach that holes and slits both provide the same function of permitting medicine to pass through and be applied to a patient. The fact that Abiuso et al. disclose that the term "holes" is intended to include slits emphasizes that holes and slits serve the same purpose. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Lampropoulos et al. slits for a hole, as taught by Abiuso et al. because Abiuso et al. teach that slits and holes are functional equivalents.

However neither Lampropoulos et al. nor Abiuso et al. teach that the holes have a non-variable, combined cross-sectional flow area that is less than the flow area of the lumen of the catheter so that the holes define a flow restricting orifice of the catheter. These limitations however are taught by Loeffler in view of Saab.

Loeffler teach a catheter having irrigation ports (1, 2) on the side walls of the catheter (see col. 6, lines 35-36). Loeffler teach that the size, shape and orientation of the perfusion ports can be changed as needed (col. 6, lines 38-42.) .

Moreover, Saab teaches that by adjusting the diameter of a catheter tube, the cross-sectional area of a lumen may be varied to create different pressure gradients and fluid flow rates (col. 11, lines 50-53).

In short, Loeffler teaches that the size of the holes can be changed as needed (col. 6, lines 38-42), and Saab teaches that the diameter of a catheter tube may be adjusted to create different pressure gradients and fluid flow rates as desired (col. 11, lines 50-53). Thus these references suggest that the holes of the Lampropoulos et al. catheter can be varied and the diameter of the catheter can be varied, both of which will alter the pressure gradients and fluid flow rates as desired. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter taught by Lampropoulos et al. in view of Abiuso et al. to vary the size of the openings as taught by Loeffler because Loeffler teaches that the size of the ports can be changed as needed. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the diameter of the catheter because Saab teaches adjusting the diameter of the cross-sectional area of a lumen to create different pressure gradients and fluid flow rates, as would be desirable for achieving optimum fluid delivery using the catheter. Such variations in the hole size and lumen diameter encompass a catheter having the relative total cross-sectional flow as claimed by Applicant, that is the flow area of the lumen of the catheter being greater than the combined area of the openings. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this

case, Lampropoulos et al. in view of Abiuso et al. teach the general conditions of the claim and the opening size and number (which together make up the combined area of the slots) being less than the cross-sectional area of the lumen of the catheter are within an optimum or workable range and thus their discovery involves only routine skill in the art. (The Office also notes that the claims do not require that all of the openings in the entire catheter be less than the cross-sectional area of the lumen. That is, the elongated tube or infusion section claimed by Applicant may be considered only a portion of a catheter.)

As to the following claims, Lampropoulos et al. disclose the limitations as follows.

As to claim 5, since Lampropoulos et al. disclose the catheter, Lampropoulos therefore disclose providing the catheter, including the step of providing exit holes having a non-variable size. (It is noted that Applicant has not recited how the structural limitations of the catheter are provided).

As to claims 2 and 6, the holes are provided throughout the circumference of the catheter (see figure 6).

As to claims 7 and 11, the exit holes are in at least one row aligned with a longitudinal axis of the catheter (see fig. 16.)

Moreover, as to claim 3, Lampropoulos et al. does not disclose the specific diameter of the exit holes. However, the diameter of the exit holes that would achieve the optimum results, i.e., the most uniform delivery of fluids, as taught by Lampropoulos, can be discovered through routine experimentation and thus would be obvious. It has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

2. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampropoulos et al., 5,817,072, in view of Abiuso et al., 5,213,576, and Loeffler, 5,891,154, and Saab, 5,624,392, as applied to claim 1, and further in view of Stevens, 5,536,261.

Lampropoulos et al. in view of Abiuso et al. and Loeffler and Saab disclose the invention substantially as claimed (see above), except for the motivation to provide a closed distal end.

Stevens discloses a catheter having openings for fluid delivery in the circulatory system. Stevens teaches that the catheter has a closed distal end which encourages lateral flow as would be desirable (column 2, lines 35-37.) It would have been obvious to provide a closed end as taught by Stevens in the Lampropoulos catheter because Stevens teaches that a closed distal end provides the advantage of encouraging lateral flow as would be desirable for delivering fluid in the circulatory system.

Response to Arguments

Applicants' arguments filed October 5, 2006 have been considered but are not persuasive. Applicants argue that there is lack of suggestion or motivation to combine the prior art and that Examiner has used the Applicants' invention as a blueprint to reconstruct the claimed invention. More specifically, Applicants argue that Abiuso et al.

do not teach that slits and holes are functional equivalents but rather that the term holes can also mean slits. Applicants assert that Abiuso et al. explain that an advantage of the slits, as opposed to the holes, is that the fluid will not bleed until a minimum pressure is applied, and thus it is clear that the holes and slits function differently and product different characteristics. This argument is not persuasive because even though the slits and holes have different characteristics and one can have an advantage over the other in a certain aspect, Abiuso et al. nevertheless teach that both slits and holes provide the same function of permitting an outflow of fluid. This is supported by the disclosure of Abiuso et al. that the holes and slits can be substituted for each other, i.e., they are interchangeable.

Applicants also argue that Loeffler provides no guidance as to the desired size of the ports or flow rate through the catheter. This argument is not persuasive because Loeffler nevertheless teaches that the size of perfusion ports can be changed as desired. As to the argument that Loeffler makes no reference to the importance or challenge of attaining uniform fluid flow over all of the perfusion ports, this is not persuasive because given the teachings of Loeffler that the size of perfusion ports can be changed as desired and the teachings of Saab that the diameter of a catheter tube can be adjusted to adjust pressure gradients and fluid flow rates, it is suggested to one of ordinary skill in the art to adjust the perfusion ports as desired and/or lumen diameter to achieve the desired pressure gradients and fluid flow rates and it is obvious that one of ordinary skill in the art can arrive at the same result given these adjustments as suggested by the prior art.

Applicants also argue that Saab does not teach adjusting the flow rate of any fluid flowing out of the lumen and into an anatomical region, but rather, the fluid in the Saab catheter re-circulates within the catheter. This is not persuasive because Saab nevertheless suggests adjusting the lumen diameter to achieve the desired flow rate or pressure gradient, and one of ordinary skill in the art would recognize that the flow rate or pressure gradient can be adjusted by changing the lumen diameter even if the fluid flow in the catheter flows into an anatomical region such as that in the Lampropoulos et al. catheter.

Applicants also argue the Loeffler reference only teaches that the holes sizes of a catheter may be altered individually and that the present invention does not deal with the optimization of the exit hole size but rather the critical relationship between the aggregate area of the exit holes and the cross-sectional area of the lumen. Applicants further argue that similarly the Saab reference discloses variation of a single parameter and makes no disclosure or suggestion of the critical relationship between the cross-sectional area of a lumen and the combined area of the exit holes. Applicants assert that Examiner has located references that address individual parameters of the claimed invention, but has not provided any suggestion or motivation to combine these references except for Applicants' own disclosure. These arguments are not persuasive because even if these teachings regarding hole and lumen sizes to adjust fluid dynamics are disclosed in individual references, the teachings nevertheless suggest that these parameters can be adjusted and the variations in these parameters encompass those claimed by Applicants.

Applicants further argue that even if the proposed combination were proper, Applicants' submit that the relationship of the claimed invention is a critical relationship that is essential to the operation of the claimed catheter. Applicants point to MPEP 2144.05 IIA in which an optimized range is unpatentable unless the range is shown to be critical. Applicants submit that the claimed range is critical because if a catheter was constructed with an aggregate area of exit holes that is significantly larger than the cross-sectional area of a lumen then the catheter would not be able to deliver uniform fluid flow throughout the length of the infusion section of the catheter. Applicants assert that because the relationship has been shown to be critical to a main function of the claimed invention, it weighs in favor of the patentability, even if the proposed combination were proper. This is not persuasive because given the teachings of the prior art in adjusting the port size and catheter lumen size to affect pressure gradient and fluid flow rate, one of ordinary skill in the art can arrive at the same result given the suggestion to adjust these variables and one of ordinary skill in the art would expect the fluid flow rates to be adjusted according to the different port and lumen sizes. The fact that the claimed relationship will produce a uniform delivery of fluid need not even be an intended result. For example, a skilled artisan is suggested by the prior art to select a certain lumen size that will produce the desired flow rate in the Lampropoulos et al. catheter and it is not unexpected that such adjustments encompass Applicants' claimed relationship, nor is it unexpected that such adjustments in parameters result in a fluid flow rate that provides for uniform delivery, especially in view of the disclosure by Lampropoulos et al. of increasing hole sizes along the length of the catheter so that fluid

flow will flow substantially all of said exit holes at a substantially equal rate (col. 7, lines 57-67). Given this particular teaching by Lampropoulos et al., the catheter can be provided such that there is uniform delivery given a variety of hole sizes and lumen sizes (the adjustments of which are suggested by Loeffler and Saab), so long as the holes increase in size as appropriate for equal flow rate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ANN YEN LAM
PATENT EXAMINER